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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,576	11/06/2000	Charles L. Magness	55382-3	9656

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EXAMINER	
SKIBINSKY, ANNA	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/707,576	MAGNESS ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14-26,28, 31-44 and 46-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,14-26,28,31-44 and 46-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

Detailed Action

Applicants' arguments, filed May 2, 2005, have been fully considered but they are not deemed persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

1. The following is an Office Action in response to the communication received on May 2, 2005. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 2, 2005 has been entered.

Claims 1 and 20 have been amended. Claims 1-10, 14-26, 28, 31-44, and 46-55 are now pending in this application.

Response to Amendment

2. Applicant's amendments of claims 1 and 20 are acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 1-10, 14-26, 28, 31-44 and 46-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the entirety of the Applicant's disclosure as filed has revealed that several limitations in the claim set submitted on May 2, 2005 do not have written basis as filed and therefore are deemed as new matter.

Specifics of the new matter limitations are explained as follows. Because the specification does not teach or provide support for these limitations the following is deemed as the insertion of new matter:

a. Claim 1 has been amended to recite, "using data related to the identified genetic variations between the ARA sub-population and the ARU sub-population to identify the target associated with the selected biological condition." Individual concepts of identifying a drug target based on genetic difference between ARA, ARU, URU (in

Claim 13) and classifying the population into sub-populations ARA, ARU, and URU by the selected biological condition (in Claim 15) are disclosed as filed but the connection between the two as amended in Claim 1 is not found. The specification (page 26, lines 22-28) discusses metabolic testing to stratify the population into sub-populations and also that metabolic testing is important when seeking to identify a drug target associated with a biological condition. However, using the data from the genetic differences between the ARA and ARU sub-populations to identify a drug target for a selected biological condition is not disclosed.

b. Claim 20 has been amended to recite "A computer-implemented method of data analysis to identify target for use in treating a selected biological condition, comprising, ... identifying one or more targets for use in treating the selected biological condition ..."

The method of identifying the target with the use of a computer is not described in the specification. Pages 14-17 describe the computer system and environment needed to carry out the classification method described by the invention however, no directions and necessary parameters are provided to explain the use of a computer to identify a drug target used in treating a selected biological condition.

c. Claims 31-33 have been amended to recite, "... wherein identifying one or more targets comprises identifying a [drug target, diagnostic assay, vaccine] based on the genetic differences between genetic test results ..." The specification does not recite a method for identifying one or more targets by identifying a "drug target based on genetic differences ..." (Claim 31), "diagnostic assay based on genetic differences ..."

(Claim 32), or "vaccine based on genetic differences ..." (Claim 33). Mention of the usefulness of genetic analysis of the ARU sub-population for forming a basis for diagnostic assay or vaccine development is on page 24, lines 14-16. This is insufficient to deem identifying one or more drug targets through identifying a drug target, diagnostic assay, or vaccine as being part of the claimed invention.

d. Claim 41 has been amended to recite "A system for data analysis to identify a target for treating selected biological condition, comprising ... a processor to: analyze genetic test result data to determine genetic differences between the subjects in the ARA category ad the ARU category; and identify a target for treating the selected biological condition" Though processing devices are mentioned on page 14, lines 27-28, of the specification there are no disclosed connections between using a processor (used in classifying sub-populations ARA, ARU, and URU) and the identification of a target.

e. Newly added Claims 47-50 recite further limitations on claim 1 "wherein identifying a target comprises ..." Methods of identifying a "target," "diagnostic assay," "vaccine component," and "drug component" based on the test results from group ARU and ARA are not described within the specification or covered by the scope of the previous claims, as explained in d. above

f. Newly added claims 50 and 51 recite further limitations on claim 20 "wherein identifying a target comprises identifying a drug component ..." Identifying a drug component based on the test results from group ARU and ARA are not described within the specifications or covered by the scope of the previous claims.

g. Newly added claim 52 recites the limitation of "The system of claim 41 wherein the processor is configured to identify a drug target based on genetic variations ..." Processing devices are mentioned on page 14, line 27-28 but, configuration of a processor based on genetic variations for the purpose of identifying a drug target is not cited as being part of the claimed invention.

h. Newly added claims 53-55 which depend from claim 41 limit the configuration of the processor to identifying a drug component, a diagnostic assay, and a vaccine component, based on genetic variations determined from tests on group ARA and ARU. The method for "identifying" a drug component, diagnostic assay and vaccine are not described in the specifications. Implementing a processor to identify a drug component, diagnostic assay and vaccine are is also not described in the specification and therefor not deemed to be part of the invention as originally filed.

Enablement

Claims 1-10, 14-26, 28, 31-44 and 46-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which were not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at

1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

(1) the quantity of experimentation necessary

The identification of a drug target is briefly discussed in the specification, page 13, lines 14-20. However, necessary methods, time and materials for drug target identification are not discussed in the specification. The identification of a drug target requires knowledge of the cause of disease and the biological systems associated with it. Drug target identification currently requites several months to years of research and costs hundreds of millions of dollars per drug.

(2) the amount or direction presented

Steps and laboratory procedures for drug target identification are not discussed in the specification. Page 25 (line 19) through page 30 (line 8) lists "steps that are taken to analyze a population and define affected status, risk factors and the characterization of the ARA, ARU, and URU phenotypes. Page 30 (line 10) through page 34 (end of specification) details the method for analyzing an individual in a population based on comparisons with the sub-populations of phenotypic groups determined with the invention. Directions in the specification are mainly aimed at describing the methods of classifying the population into sub-populations.

(3) the presence or absence of working examples:

Examples in the specification are directed towards the method and means of achieving the classification of the population into the ARA, ARU, and URU groups. No examples of drug target identification are given.

(4) the nature of the invention:

The nature of drug target identification is briefly discussed on page 13, lines 14-20. Inventions revolving around drug target identification are complex in nature. Currently, clustering algorithms are used to organize expression data into relevant groups. These clustering analysis techniques are computationally expensive. Information gained such as expression profiles from healthy and disease cells are compared to understand the role played by specific genes and proteins in the disease process. These computational tools serve to produce a detailed picture of a protein family's involvement in a disease process and it's potential as a drug target. Bioinformatics methods have also been developed to virtually screen the target for compounds that bind and inhibit the protein in such a way as to not disrupt normal metabolism.

(5) the state of the prior art:

The usefulness of the invention for drug target identification is briefly discussed (page 9 lines 20-21 and 26-21) though prior art related to drug target development is not discussed. Genomic based drug discovery involves the use of computers to store, organize, and analyze the data coming from wet lab

experiments in the fields of physiology, biochemistry, molecular biology, genetics, genomics, and proteomics. Genomic databases are employed by researchers find drug targets through the comparison of functional information of thousands of genes. Techniques such as clustering analysis have been available for over thirty years and are employed by those in the field of microarray research.

(6) the relative skill of those in the art:

Level of skill in the art needed to carry out drug target identification using results from the method to classify phenotypes is not discussed. The process of drug target identification employs skill from the fields of genomics, proteomics, and bioinformatics. The successful discovery of one drug target costs hundreds of millions of dollars and a period or research time that can span several years. The level of skill in the art of drug target identification can be assumed to be high, such as that possessed by individuals with post graduate level research experience in the fields of molecular biology, bioinformatics, and pharmaceutical development.

(7) the predictability or unpredictability of the art:

This is not discussed as filed pertaining to drug target identification. Drug target identification is a long process of trial and error requiring months to several years or research per drug target.

(8) the breath of the claims:

Identifying and understanding the specific biological condition for which a drug will be developed is an additional complex process that adds to the complexity of drug target development. The instant claims are not limited to a biological condition associated with a target, which is identified via the instant claims and are thus extremely broad. This results in the inclusion of optionally all diseases and other biological conditions.

The Board also stated that although the level of skill in drug target identification is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

There is undue experimentation required to go from the classification results achieved by implementing the invention to drug target identification without some prior knowledge of a relationship between a potential target and a biological condition as claimed. The specification provides descriptions for the collecting and scoring of data from the population to achieve the final classification of sub-populations in ARU, ARA, and URA. However, the details for identifying a drug target based on the classification are not described. Thus, there is not sufficient support to enable one skilled in the art of make or use the invention. The specification recites (page 13, lines 16-20), "As those skilled in the art can appreciate, this type of genotypic evaluation is significant within the present invention due to the classification of subjects into the phenotypic categories discussed above. That is, the discovery of genetic drug targets become a valuable tool

when the ARU phenotype is compared against other sub-population." Though the statement points out the usefulness of the described classification method for the identification of drug targets, it does not specifically describe the invention as containing a method for identifying drug targets nor does it describe the method, experimental or computational, for identifying drug targets. The identification of a drug target requires the sorting out of 1000's of targets present in most organisms. Because the method of identifying a drug target based on genetic differences between two groups is not trivial and requires years to complete by someone skilled in the art, the general mention of the method in the specifications of the instant application is not sufficient to deem it as being part of the invention.

Vague and Indefinite

Claims 1-10, 14-19, and 47-50 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "ought to be affected" in claim 1, line 14, is vague and indefinite because it lacks clear and concise wording as to why members of the ARU sub-population "ought to be affected." The said phrase is probably indicative of targets to be identified through their relationship to a selected biological condition but is not clearly and concisely set forth in the claim wording. This vague and indefinite wording carries forth to claims dependent from instant claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejections of Claims 1-10, 14-26, 28, 31-44 and 46-55 under 102(a) in the prior Office Action mailed January 3, 2005 are maintained. The prior art of NIH's risk assessment models, as cited in the previous Office Action, does apply to the scope recited by the claims and Applicant is arguing limitations that are not presently found in the claims.

The following articles were used in the prior Office Action to describe the breast cancer screening methods established by NIH:

- "Susceptibility to Breast Cancer," Clinical Study started on February 8, 2000 (referred to hereinafter as reference A),
- "Genetic Testing for Breast Cancer Risk: It's Your Choice," August 14, 1997 (referred to hereinafter as reference B).
- "Risk Communication in Clinical Practice: Putting Cancer in Context," 1999 (referred to hereinafter as reference C),
- "Validation Studies for Models Predicting the Risk of Invasive and Total Breast Cancer Incidence," September 15, 1999 (referred to hereinafter as reference D),

and

- Archived version of the National Cancer Institute's Breast Cancer Risk Assessment Tool, June 20, 2000 (referred to hereinafter as reference E).

Applicant's arguments are deemed not persuasive for the following reasons:

The Gail Method is used to assess the risk of developing breast cancer if an individual's family history does not imply a hereditary disposition for breast cancer (i.e. if there are no mutations in the BRAC1 or BRAC2 gene). The majority of breast cancer cases are not due to inherited alterations in the BRCA1 or BRCA2 genes.

The Breast Cancer Risk Assessment Tool (BCRAT) provided by the NIH bases the calculation of risk on the Gail Model which uses statistical methods applied to data collected and categorized during the Breast Cancer Detection and Demonstration Project (BCDDP), a mammography screening project conducted in the 1970's. The Appendix in Reference D shows that the probability of an individual developing breast cancer is calculated with the Gail Model and data gathered by the BCDDP (Appendix Table 1).

Using NIH's BCRAT, a physician compares an individual's relevant history (collected as shown in reference E) against data from the BCDDP to assess the individual's risk of contracting breast cancer. When the individual's data is compared with data from the BCDDP, the individual is classified into a category with a specific risk of developing breast cancer in 5 years and lifetime. Therefor, the NIH Risk Assessment Tool, based on the Gail Model, does employ a classification method. For example, a

woman who begins menstruating before the age of 12, has children after the age of 30, and/or begins menopause after the age of 50 can be classified into a group that is at a higher risk of developing breast cancer.

Since the risk of developing breast cancer for a woman is known to be about 10-13%, most if not all American physicians recommend that a woman undertake a mammography screening at least once in her life. Thus, it can be considered that all women are "At Risk" in developing breast cancer. In other words, all women can be classified as members of a population that "ought to be effected by the selected biological condition at the present time based on a risk analysis" (Claim 1, lines 13-14). The NIH Risk Assessment Tool serves to match an individual's history with the data collected in the BCDDP thus, classifying that individual into a group with a specific risk of developing breast cancer in 5 years and lifetime.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number and email address are (571) 272-4373. The examiner can normally be reached on 8 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 8/22/05

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER